# *OAR Box 1158*

***Prepped by Ryan Dugan***

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CONTACT REPORT--MRI Project No. 7712-K

From: David L. Newton and Sharon Srebro
Environmental Engineering Department

Date of Contact: 5/9/86 and 10/04/88 (for revisions)

Contacted by: Telephone

Company/Agency: Johnson & Johnson, International
New Brunswick, New Jersey

Telephone Number: (201) 524-2978
Fax (201) 214-0332
214-0334

CONFIRMATION
RESPONSE See attached Telecon
WRITTEN ☐
VERBAL X
NONE ☐

Person(s) Contacted/Title(s)

Mr. Miron G. Popescu, Technical Advisor

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A followup call to confirm the information in the original contact report (see attached) was conducted October 4, 1988, by Sharon Srebro. Mr. Popescu provided verbal revisions that are incorporated in this version of the report. (see also telecon dated October 4, 1988, Sharon Srebro with Miron Popescu.)

CONTACT SUMMARY:

I called Mr. Popescu to discuss EO sterilization processes and EO emissions from sterilization chamber evacuation cycles and aeration cycles.

Mr. Popescu said that one can fairly accurately model EO behavior in an empty sterilization chamber by using ideal gas relationships. For example, if a 600 $ft^3$ chamber is charged with 50 lb of 80/20 EO/$CO_2$ mix at an operating pressure of 0.9 atm, the EO concentration would be approximately 1,000 mg/ℓ. If the chamber is evacuated to 1 in. Hg absolute (or 0.03 atm absolute), approximately 0.81 lb of sterilant gas are left in the chamber, or approximately 49 lb of sterilant gas are removed.

I asked Mr. Popescu how such a calculation would compare with actual data. Mr. Popescu responded that measurement data were available, and that typically one would measure concentrations of 600,000 to 700,000 ppmv at about 6 in. from the stack exit during the first evacuation cycle.

Mr. Popescu said that the common practice of vacuum pulsing (pulsating purge) only serves to remove EO adsorbed on the chamber walls, but does not remove EO absorbed in the product to any significant extent. He said that this practice helps to lower worker exposure to EO when the chamber doors are opened and products unloaded. He said that vacuum pulsing would remove perhaps another 10 percent of the remaining 0.81 lb in the hypothetical case discussed earlier. This would result in maximum stack concentrations of 3,000 to 4,000 ppmv.

Mr. Popescu said that a 3 to 7 day aeration period is typical for products after they have been removed from the sterilization chamber. During aeration, products may be exposed to heat and airflow, but according to Mr. Popescu, time is the essential element for removing absorbed EO from the product. He said that FDA requires that EO concentrations in most products be no higher than 250 ppmw. Certain surgical implants may require lower concentrations. Mr. Popescu said that roughly 80 percent of the material originally absorbed by the product is desorbed within 7 days.

Mr. Popescu said that a good contact for information on absorption of EO and EO chemistry during sterilization processes is Mr. Ed Gunsales at the Johnson & Johnson plant in Valley Forge, Pennsylvania. He can be reached at (215) 337-2400.

CONTACT REPORT--MRI Project No. 7712-K

From: David L. Newton, Environmental Engineering Department

Date of Contact: 5/9/86

Contacted by: Telephone

Company/Agency: Johnson & Johnson, International
New Brunswick, New Jersey

Telephone Number: (201) 524-5483

Person(s) Contacted/Title(s)

Mr. Miron G. Popescu, Technical Advisor

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CONTACT SUMMARY:

I called Mr. Popescu to discuss EO sterilization processes and EO emissions from sterilization chamber evacuation cycles and aeration cycles.

Mr. Popescu said that one can fairly accurately model EO behavior in the sterilization chamber by using ideal gas relationships. For example, if a 600 $ft^3$ chamber is charged with 50 lb of 80/20 EO/$CO_2$ mix at an operating pressure of 0.9 atm, the EO concentration would be approximately 1,000 mg/ℓ. If the chamber is evacuated to 1 in. Hg absolute (or 0.03 atm absolute), approximately 1.81 lb of sterilant gas are left in the chamber, or approximately 48 lb of sterilant gas are removed.

I asked Mr. Popescu how such a calculation would compare with actual data. Mr. Popescu responded that measurement data were available, and that typically one would measure concentrations of 600,000 to 700,000 ppmV at about 6 in. from the stack exit during the first evacuation cycle.

Mr. Popescu said that the common practice of vacuum pulsing (pulsating purge) only serves to remove EO adsorbed on the chamber walls, but does not remove EO absorbed in the product to any significant extent. He said that this practice helps to lower worker exposure to EO when the chamber doors are opened and products unloaded. He said that vacuum pulsing would remove perhaps another 10 percent of the remaining 1.81 lb in the hypothetical case discussed earlier. This would result in maximum stack concentrations of 3,000 to 4,000 ppmV.

Mr. Popescu said that a 3 to 7 day aeration period is typical for products after they have been removed from the sterilization chamber. During aeration, products may be exposed to heat and air flow, but according to Mr. Popescu, time is the essential element for removing absorbed EO from the product. He said that FDA requires that EO concentrations in products be no higher than 250 ppmL. Mr. Popescu said that roughly 80 percent of the material originally absorbed by the product is desorbed within 7 days.

Mr. Popescu said that a good contact for information on absorption of EO and EO chemistry during sterilization processes is Mr. Ed Gunsales at the Johnson & Johnson plant in Valley Forge, Pennsylvania. He can be reached at (215) 337-2400.